IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF
CALFIFORNIA SOUTHERN DIVISION

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In re: FOSAMAX PRODUCTS
LIABILITY LITIGATION

----------X

JACQUELINE HILL,

Plaintiff,

v.

MERCK & CO., INC.,

Defendant.

----------X

Civil Action No. SACV08-65 AHS(ANx)

COMPLAINT FOR DAMAGES
(Products Liability-Personal Injury)

JURY TRIAL DEMANDED

PLAINTIFF'S ORIGINAL COMPLAINT

Jacqueline Hill (hereinafter "Plaintiff"), by and through her undersigned counsel, sues Merck & Co., Inc., and states as follows:

1. This is a civil action brought on behalf of Plaintiff regarding personal injuries and damages that were a result of her ingestion of Fosamax® which was designed, manufactured, tested, marketed, distributed and sold to Plaintiff by Merck & Co., Inc. and/or its representatives.

I.

PARTIES

2. Plaintiff is a citizen and resident of the State of California, residing in Laguna Beach, California, County of Orange.

I/S
S-20
365

3. Defendant Merck & Co, Inc. (hereinafter "Defendant" or "Merck") is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100. Service of process may be accomplished by serving Merck & Co., Inc.'s Chief

Financial Officer, Richard T. Clark, at Merck's principal office address of 1 Merck Dr., Whitehouse Station NJ 08889.

4. At all relevant times herein, Defendant, through its agents, servants and employees, was the designer, manufacturer, marketer, advertiser, distributor, and seller of the prescription medication, Fosamax®, which is the brand name of alendronate sodium (hereinafter "Fosamax").

II.

JURISDICTION AND VENUE

5. Jurisdiction of this Court exists, pursuant to 28 U.S.C. § 1332, because Plaintiff is a citizen of a state other than the state in which the Defendant is incorporated and/or has its principal place of business, and the matter in controversy exceeds Seventy-five Thousand and no/100 dollars ($75,000.00), exclusive of interest and costs.

6. Venue is proper pursuant to 28 U.S.C. § 1391. Defendant has sufficient minimum contacts with California or otherwise intentionally avails itself of the consumer markets within California through the promotion, sale, marketing and/or distribution of its products in the State to render the exercise of jurisdiction by the California courts permissible under traditional notions of fair play and substantial justice.

7. This action includes claims for injuries to Jacqueline Hill caused by her ingestion of Fosamax and therefore should be, and Plaintiff consents to, transfer to Multidistrict Litigation No. 1789 In Re: Fosamax Products Liability Litigation, United States District Court, Southern District of New York.

III.

CONDITIONS PRECEDENT

8. All conditions precedent have been performed or have occurred.

IV.

FACTUAL BACKGROUND

A. Fosamax Information

9. Fosamax was approved by the United States Food & Drug Administration ("FDA" herein) in September 1995. FDA-approved uses include the treatment of Paget's Disease and the prevention and treatment of osteoporosis.

10. Fosamax falls within a class of drugs known as bisphosphonates, which are used to treat bone conditions. Other drugs within this class, such as Aredia and Zometa, are also used as an adjunct to chemotherapy, but are not indicated for use in non-cancerous conditions such as osteoporosis.

11. There are two classes of bisphosphonates: nitrogenous (containing nitrogen) and non-nitrogenous (no nitrogen). Fosamax, Aredia, and Zometa are included in the nitrogenous bisphosphonates.

12. Fosamax is the world's top-selling bisphosphonate. It is Merck's second best-selling drug, with sales in 2005 of $3.2 billion, according to the Associated Press. In the U.S. alone, more than 22 million prescriptions were written last year, according to the drug research firm IMS Health.

B. Defendant's Failure to Warn of the Dangers of Fosamax

13. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent occurrence of osteonecrosis of the jaw ("ONJ" herein) in cancer patients using nitrogenous bisphosphonates, i.e., Aredia and Zometa. These drugs also have known gastrointestinal side effects which also occur with Fosamax. Defendant knew or should have known that Fosamax, as a

nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass.

14. Merck knew or should have known that bisphosphonates, including Fosamax, inhibit endothelial cell function; inhibit vascularization of the affected area; and induce ischemic changes to patients' lower and upper jaws (mandibles and maxillae) and that these ischemic changes appear to be cumulative in nature.

15. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That, in turn, can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

16. Dentists are now being advised by dental associations to refrain from using invasive procedures (such as drilling a cavity) for any patient on Fosamax.

17. Shortly after Fosamax was released, the FDA began receiving reports of ONJ and other dental complications among Fosamax users, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates.

18. Despite this knowledge, Defendant failed to implement further studies regarding the risk of ONJ relative to Fosamax; Defendant proposed further uses of Fosamax, such as Fosamax-D; and sought to extend the exclusivity period of Fosamax through 2018.

19. ONJ is a serious medical event involving severe deterioration and decompensation of the jaw bones, is very difficult to treat once the patient is symptomatic, and can result in severe permanent disability and death.

20. By 2002 or earlier, Defendant knew or should have known that physician reports of Aredia patients suffering from ONJ showed a possible causal link between the use of ONJ and bisphosphonates.

21. Medical research published in 2004 revealed a link between ONJ and the use of bisphosphonates Aredia and Zometa. According to the report, "The jaw complications presented ... had a major negative effect on the quality of daily life for each of these patients" and "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," *Journal of Oral and Maxillofacial Surgery*, vol. 62, p. 533 (2004).

22. In September 2004 and May 2005, the manufacturer of bisphosphonates Aredia and Zometa sent warnings to health care professionals regarding the risk of ONJ associated with these drugs. Warnings were added to the Aredia and Zometa labels in August and November 2004, respectively.

23. On August 25, 2004, the FDA posted its Office of Drug Safety Postmarketing Safety Review on bisphosphonates (specifically Aredia, Zometa, Actonel, and Fosamax). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

24. Based on their review, the FDA observed that the risk of ONJ was not confined to bisphosphonates used for chemotherapy, but rather, was a class effect which specifically extended to the oral bisphosphonate, Fosamax.

25. As a result, the FDA recommended and stated that Merck should amend the Fosamax labeling to specifically warn about the ONJ risk.

26. Merck has refused to accede to the FDA's request and to this day, the Fosamax labeling still contains no warning about the risk of ONJ.

27. Despite Defendant's knowledge about the increased risk of ONJ and other serious dental and oral complications in Fosamax patients, Defendant continues to defend Fosamax and minimize unfavorable findings rather than warn patients and the medical community.

C. Plaintiff's Use of Fosamax and Resulting Injury

28. Plaintiff used Fosamax as prescribed and in a foreseeable manner for the treatment or prevention of osteoporosis.

29. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of ONJ and other serious oral and dental conditions resulting from Fosamax use and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

30. At all relevant times herein, there were safer alternative products available to consumers, including Plaintiff, to prevent and treat osteoporosis.

31. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking Fosamax.

32. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

33. As a direct and proximate result of using Fosamax, Plaintiff suffered severe jaw bone deterioration leading to osteonecrosis of the jaw.

V.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

34. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment and by the inherently undiscoverable nature of Plaintiff's injuries.

35. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her prescribing physicians the true risks associated with taking Fosamax. As a result of Defendant's actions, Plaintiff and her prescribing physicians, were unaware and/or could not have reasonably known or learned that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

36. Furthermore, Defendant is estopped from relying on any statute of limitations because of its fraudulent and/or intentional concealment of the true character, quality and nature of Fosamax. Defendant was under a duty to disclose the true character, quality and nature of Fosamax because this was non-public information over which the Defendant had and continues to have exclusive control, and because the Defendant knew that this information was not available to Plaintiff or her medical providers.

37. Plaintiff had no knowledge that Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment by Defendant, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendant had the ability to spend and did spend enormous amounts of money in

furtherance of its purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely solely on Defendant's representations.

38. Furthermore, the nature of Plaintiff's injuries and their relationship to Fosamax use was inherently undiscoverable. Consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff discovered, or by the exercise of reasonable diligence and intelligence should have discovered, that she had a basis for an actionable claim. Plaintiff did not have knowledge of facts that would lead a reasonable person to investigate and discover Defendant's tortious conduct. Under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

VI.

CAUSES OF ACTION

Count I:

Negligence

39. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

40. Defendant had a duty to exercise reasonable or ordinary care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax, including a duty to assure that consumers, like Plaintiff, did not suffer unreasonable adverse side effects, such as ONJ and a duty to warn consumers, including Plaintiff, of the serious risks associated with Fosamax use.

41. Defendant breached its legal duty by not exercising due care. Defendant knew or should have known that Fosamax created an unreasonable risk of ONJ and despite this knowledge, continued to market, distribute, and sell Fosamax to the public, including Plaintiff. Further, Defendant failed to conduct proper testing and failed to adequately warn and instruct consumers, including Plaintiff, about the risk of suffering serious harm from Fosamax use.

42. Defendant's conduct as described herein constitutes the violation of statutes, ordinances, and/or rules and regulations, including those promulgated by the FDA. Said statutes, ordinances, rules and regulations were designed to protect the health, safety, and welfare of the general public, including Plaintiff, from injuries such as those caused by Fosamax. Defendant had no excuse for its violative conduct and said conduct proximately caused Plaintiff's personal injuries complained of herein.

43. As a direct and proximate cause of Defendant's negligence in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax, Plaintiff has suffered and will continue to suffer injuries and monetary damages.

Count II:

Strict Liability - Design Defect

44. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

45. Fosamax *as* designed, manufactured and sold by Defendant was placed into the stream of commerce by Defendant in a defective and unreasonably dangerous condition, taking into consideration the utility of the product and the risks involved with the drug's use.

46. Fosamax as designed, manufactured and sold by Defendant was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

47. Fosamax as designed, manufactured and sold by Defendant, was expected to reach and did reach consumers, including Plaintiff, without substantial change or alteration of the product.

48. Plaintiff used Fosamax as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant. However, Fosamax failed to perform safely.

49. Fosamax as designed, manufactured and sold by Defendant was defective due to inadequate testing.

50. As a direct, producing, and proximate result of the defective condition of Fosamax as designed, tested, developed, manufactured, marketed, and sold by Defendant, Plaintiff has suffered and will continue to suffer injuries and monetary damages.

Count III:

Strict Liability - Failure to Warn

51. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

52. Defendant's marketing of Fosamax was defective because Defendant failed to give adequate warnings of the dangers of Fosamax that were known or should have been known by Defendant, including ONJ; and/or because Defendant failed to give adequate instructions to avoid such dangers, which failure rendered Fosamax unreasonably dangerous as marketed.

53. As a direct, producing, and proximate result of Defendant's failure to properly warn physicians and consumers, Plaintiff has suffered and will continue to suffer injuries and monetary damages.

Count IV:

Breach of Express Warranty

54. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

55. Defendant expressly warranted, by and through statements made by Defendant or its authorized agents, that Fosamax was safe, effective, and fit for its intended use.

56. Plaintiff and her physicians relied on the skill, judgment and representations of Defendant.

57. Fosamax did not conform to Defendant's express warranties in that it was not safe and fit for its intended use because it caused serious and permanent adverse side effects, including ONJ.

58. As a direct and proximate result of Defendant's breach of its express warranties, Plaintiff has suffered and will continue to suffer injuries and monetary damages.

Count V:

Breach of Implied Warranty

59. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

60. Defendant impliedly warranted to Plaintiff and her physicians that Fosamax was of merchantable quality and was safe and fit for its intended use.

61. Plaintiff and her physicians relied on Defendant's skill and judgment.

62. Fosamax was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including ONJ.

63. As a direct and proximate result of Defendant's breach of its implied warranties, Plaintiff was caused to suffer and will continue to suffer injuries and monetary damages.

Count VI:

Deceptive Trade Practices

64. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

65. Defendant engaged in commercial conduct by selling Fosamax.

66. Defendant misrepresented, omitted, and/or concealed material information regarding Fosamax by failing to disclose known risks. Defendant engaged in unfair, unconscionable, deceptive and/or fraudulent acts or practices when it failed to adequately warn consumers and the medical community of the safety risks associated with Fosamax. By failing to disclose the known dangers and risks of Fosamax, Defendant engaged in unfair and deceptive consumer-oriented acts.

67. Reasonable consumers, including Plaintiff, were injured by Defendant's unfair and deceptive acts and/or practices. As a direct and proximate result of Defendant's deceptive, unfair, unconscionable and fraudulent conduct, Plaintiff has suffered and will continue to suffer personal injuries and economic damages.

68. Furthermore, Defendant's conduct was committed knowingly, willfully, and/or intentionally, thereby entitling Plaintiff to three times the actual damages sustained and such other relief as the court considers necessary and proper, in accordance with the applicable law.

Count VII:

Fraudulent Misrepresentation

69. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

70. Defendant, in the course of its business, fraudulently represented to the medical community and to Plaintiff and the general public that Fosamax had been adequately tested and was a safe and effective drug. Said representation was material and was false.

71. At the time, Defendant knew said representation was false, or made said representation recklessly, as a positive assertion, and without knowledge of its truth. Defendant knew or should have known that Fosamax had not been adequately tested, was defective in nature, and did not carry adequate warnings and instructions.

72. Defendant made said representations with the intent of defrauding and deceiving the general public, Plaintiff, and the medical community so as to increase sales of Fosamax. This shows Defendant's callous and reckless indifference to the health, safety, and welfare of Plaintiff and the general public.

73. Plaintiff reasonably relied on Defendant's false representations in choosing to ingest Fosamax.

74. As a result of Defendant's fraudulent representations, Plaintiff has suffered and will continue to suffer from serious personal injuries and monetary losses.

Count VIII:

Negligent Misrepresentation

75. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

76. Defendant, in the course of its business, made false representations to the medical community, and to Plaintiff and the public in general, that Fosamax was a safe and effective drug.

77. Defendant, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Fosamax, in that it made such misrepresentations when it knew, or reasonably should have known, of the falsity of such representations. Alternatively, Defendant made such misrepresentations without exercising due care to ascertain the accuracy of said representations.

78. Defendant supplied false information for the guidance of others. Defendant, through its misrepresentations, intended to induce reliance by Plaintiff, other consumers, and the medical community.

79. Plaintiff and her physicians justifiably relied on Defendant's misrepresentations.

80. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has suffered and will continue to suffer injuries and monetary losses.

Count IX:

Fraud and Deceit

81. Defendant conducted research and used the drug Fosamax as part of their research.

82. As a result of Defendant's research and testing, or lack thereof, Defendant distributed blatantly and intentionally false information including, but not limited to, assuring the public,

Plaintiff, the medical community, and/or the FDA that Fosamax was safe to use for the treatment and prevention of osteoporosis.

83. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, Plaintiff, the medical community, and/or the FDA.

84. Defendant had a duty to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff, the medical community or the FDA.

85. The information distributed by Defendant to the public, Plaintiff, the medical community, and/or the FDA included, but was not limited to, reports and press releases and contained material representations of fact and/or admissions.

86. The information distributed by Defendant to the public, Plaintiff, the medical community and/or the FDA intentionally included representations that Fosamax was safe to treat and prevent osteoporosis and was not injurious to the health and/or safety of its intended users.

87. Said representations were material, false and misleading.

88. Defendant knew said representations were false.

89. Upon information and belief, Defendant intentionally suppressed, ignored, and disregarded test results not favorable to the Defendant, and results that demonstrated that Fosamax was not safe as a means to treat and prevent osteoporosis.

90. In making the foregoing false representations, Defendant intended to deceive and defraud the public, Plaintiff, the medical community, and the FDA; to gain their confidence by falsely ensuring that Fosamax was safe and fit for its intended use; and to induce the public, including Plaintiff to use Fosamax.

91. Defendant made claims and representations in its documents submitted to the FDA, the public, and Plaintiff that Fosamax did not present serious health and/or safety risks.

92. When Defendant made the false representations described herein, Defendant knew said representations were false.

93. Defendant willfully and intentionally failed to disclose material facts regarding the dangerous and serious safety concerns of Fosamax by concealing and suppressing said facts.

94. Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts, and made false representations with the purpose and design of deceiving and lulling Plaintiff into a sense of security so that Plaintiff would rely on the representations and purchase, use, and rely on Fosamax and/or that her health care providers would do the same.

95. Plaintiff believed Defendant's representations to be true at the time they were made and reasonably relied on said representations.

96. At the time the representations were made, Plaintiff did not know the truth and could not have discovered the truth using due diligence, regarding the dangerous and serious health and/or safety concerns of Fosamax.

97. Defendant's aforementioned conduct constitutes fraud and deceit and was committed and/or perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

98. As a result of Defendant's foregoing acts and omissions, Plaintiff has suffered and will continue to suffer personal injuries and monetary losses.

VII.

DAMAGES

A. Compensatory Damages

99. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

100. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff suffered from severe jaw bone deterioration leading to ONJ, a painful disfiguring irreversible condition that now increases her personal risk for other dental complications, severe disability and death. As a result, Plaintiff suffers from mental anguish and diminished enjoyment of life. Further, she has incurred and will continue to incur medical costs for oral and maxillofacial care, including but not limited to hospitalizations, prescription medications, medical care, and treatment supplies. Plaintiff has already undergone two surgeries to remove both the left and right mandibular torus where the necrotic or dead jaw bone had separated itself from the normal bone. Her condition has caused and will continue to cause severe pain and disfigurement.

101. Additionally, Plaintiff has suffered from loss of earnings and/or a diminution in earning capacity as a direct and proximate result of Defendant's foregoing wrongful conduct.

102. Plaintiff gives notice to Defendant that she is suing for past, present and future damages with respect to each element set out herein. Plaintiff pleads for pre-judgment interest and post-judgment interest as provided by law. Plaintiff expressly reserves the right to amend this Petition to plead an increase in damages sought herein.

103. Plaintiff is entitled to, and seeks herein, the following elements of damage experienced in the past:

a. Physical pain and suffering;

b. Mental or emotional pain and suffering / mental anguish;

c. Loss of capacity for the enjoyment of life / diminished quality of life / physical impairment;

d. Reasonable and necessary expenses for medical care, services, and supplies actually given in the treatment of Plaintiff as shown by the evidence;

e. Loss of earning capacity, including, but not limited to, actual loss of income, if any; and

f. Disfigurement.

104. Plaintiff is further entitled to, and seeks herein, compensation for the present cash value of the following elements of damage reasonably certain to be experienced by Plaintiff in the future:

a. Physical pain and suffering;

b. Mental or emotional pain and suffering / mental anguish;

c. Loss of capacity for the enjoyment of life / diminished quality of life / physical impairment;

d. Medical expenses reasonably certain to be required in the future;

e. Loss of earning capacity, if any; and

f. Disfigurement.

B. Punitive Damages

105. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

106. Defendant's conduct complained of herein was malicious, intentional, outrageous, reckless, done with bad motives, and/or in wanton, willful, conscious, and/or deliberate disregard of

Plaintiff's rights and safety. Defendant's conduct was committed with a reckless indifference to the interest of others, including Plaintiff, the consuming public, health care professionals and the FDA.

107. At all times relevant hereto, Defendant actually knew of the defective nature of Fosamax, as set forth herein, and continued to design, manufacture, market, distribute, and sell Fosamax so as to maximize sales and profits at the expense of the public's health and safety and in wanton and willful disregard of the foreseeable serious harm caused by Fosamax. Defendant's conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, maliciousness, recklessness, and/or wanton and willful disregard for the safety and rights of Plaintiff, as well as the general public and/or consumers of Fosamax.

108. As a direct and proximate result of Defendant's conduct set out herein, Plaintiff suffered harm and is therefore entitled to punitive damages so as to punish Defendant and to deter similar conduct in the future.

C. Treble Damages

109. Defendant is liable for treble damages under the consumer protection statutes. Defendant engaged in deceptive, unfair, misleading, unconscionable and/or fraudulent conduct in violation of consumer protection statutes. Defendant's conduct was committed knowingly, willfully, and/or intentionally within the meaning of such terms as defined in said statutes.

110. Therefore, Plaintiff is entitled to and will seek three times the actual damages sustained and such other relief as the court considers necessary and proper, in accordance with the applicable law.

VIII.

DEMAND FOR JURY TRIAL

111. Plaintiff hereby demands trial by jury in this action of all issues so triable.

IX.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff requests that Defendant be cited to appear and answer herein and that upon final trial of this cause Plaintiff have judgment against Defendant for compensatory, punitive and/or treble damages as awarded by the jury plus interest, prejudgment and post-judgment, reasonable attorneys' fees, filing fees and reasonable costs of court as provided by law, and, for such other and further legal and equitable relief as this Honorable Court deems just and proper.

Respectfully submitted,

THE LAW OFFICES OF DOUGLAS M. SCHMIDT

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ATTORNEYS FOR PLAINTIFF

IX.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff requests that Defendant be cited to appear and answer herein and that upon final trial of this cause Plaintiff have judgment against Defendant for compensatory, punitive and/or treble damages as awarded by the jury plus interest, prejudgment and post-judgment, reasonable attorneys' fees, filing fees and reasonable costs of court as provided by law, and, for such other and further legal and equitable relief as this Honorable Court deems just and proper.

Respectfully submitted,

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BULLIUNG & ASSOCIATES

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ATTORNEYS FOR PLAINTIFF

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL PLAINTIFF(S) MERK & CO., INC., DEFENDANT(S).	CASE NUMBER SACV08-00065 AHS (ANx) SUMMONS

FOR OFFICE USE ONLY

FOR OFFICE USE ONLY

TO: THE ABOVE-NAMED DEFENDANT(S):

YOU ARE HEREBY SUMMONED and required to file with this court and serve upon plaintiff's attorney Gregory Bulliung, whose address is:

5012 Mission St.
San Francisco, CA 9411[illegible]

an answer to the ☒ complaint ☐ _____ amended complaint ☐ counterclaim ☐ cross-claim which is herewith served upon you within 20 days after service of this Summons upon you, exclusive of the day of service. If you fail to do so, judgement by default will be taken against you for the relief demanded in the complaint.

Clerk, U.S. District Court

Dated: JAN 18 2008

By: ROLLS ROYCE PASCHAL
Deputy Clerk

(Seal of the Court)

DOCKETED ON CM
JAN 25 2008
BY

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA

CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)
JACQUELINE CLARKE

DEFENDANTS
MERCK, & CO., INC.

(b) County of Residence of First Listed Plaintiff (Except in U.S. Plaintiff Cases):
ORANGE COUNTY

County of Residence of First Listed Defendant (In U.S. Plaintiff Cases Only):
HUNTERSON

(c) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1 U.S. Government Plaintiff
☐ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant
☑ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☑ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☑ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☑ Yes ☐ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☐ No ☐ **MONEY DEMANDED IN COMPLAINT: $**

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
28 USC 1332

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 810 Selective Service
☐ 850 Securities/Commodities /Exchange
☐ 875 Customer Challenge 12 USC 3410
☐ 890 Other Statutory Actions
☐ 891 Agricultural Act
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Info. Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes

CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise

REAL PROPERTY
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

TORTS
PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpractice
☑ 365 Personal Injury-Product Liability
☐ 368 Asbestos Personal Injury Product Liability

TORTS
PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

BANKRUPTCY
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/Accommodations
☐ 444 Welfare
☐ 445 American with Disabilities - Employment
☐ 446 American with Disabilities - Other
☐ 440 Other Civil Rights

PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence Habeas Corpus
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus/ Other
☐ 550 Civil Rights
☐ 555 Prison Condition

FORFEITURE / PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R. & Truck
☐ 650 Airline Regs
☐ 660 Occupational Safety /Health
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
☐ 820 Copyrights
☐ 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS-Third Party 26 USC 7609

VIII(a). IDENTICAL CASES: Has this action been previously filed and dismissed, remanded or closed? ☑ No ☐ Yes

If yes, list case number(s):

FOR OFFICE USE ONLY: Case Number: **SACV08-00065 AHS (ANx)**

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

VIII(b). RELATED CASES: Have any cases been previously filed that are related to the present case? ☑ No ☐ Yes as it relates to this Plaintiff

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)
- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☑ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: List the California County, or State if other than California, in which **EACH** named plaintiff resides (Use an additional sheet if necessary)
☐ Check here if the U.S. government, its agencies or employees is a named plaintiff.

Plaintiff, Jacqueline Hill resides in Orange County California.

List the California County, or State if other than California, in which **EACH** named defendant resides. (Use an additional sheet if necessary).
☐ Check here if the U.S. government, its agencies or employees is a named defendant.

Defendant is a New Jersey Corporation with its principal place business other then the State of California.

List the California County, or State if other than California, in which **EACH** claim arose. (Use an additional sheet if necessary)
Note: In land condemnation cases, use the location of the tract of land involved.

Claim arose as a result of defective drugs causing injury in the State of California.

Orange County

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ **Date** 11/16/07

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge Alicemarie H. Stotler and the assigned discovery Magistrate Judge is Arthur Nakazato.

The case number on all documents filed with the Court should read as follows:

SACV08- 65 AHS (ANx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

---

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[ ] **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

[X] **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

[ ] **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

NAME, ADDRESS & TELEPHONE NUMBER OF ATTORNEY(S) FOR, OR, PLAINTIFF OR DEFENDANT IF PLAINTIFF OR DEFENDANT IS PRO PER

Gregory J. Bulliung, Esq. CSB#144474
BULLIUNG & ASSOCIATES
5012 Mission Street
San Francisco, CA 94112
Telephone: (415) 841-9000
Facsimile: (415) 585-3300

ATTORNEYS FOR: JACQUELINE HILL

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL
Plaintiff(s),
v.
MERCK CO., INC.
Defendant(s)

CASE NUMBER
SACV08-00065 AHS (ANx)

CERTIFICATION AND NOTICE OF INTERESTED PARTIES
(Local Rule 7.1-1)

TO: THE COURT AND ALL PARTIES APPEARING OF RECORD:

The undersigned, counsel of record for JACQUELINE HILL (or party appearing in pro per), certifies that the following listed party (or parties) has (have) a direct, pecuniary interest in the outcome of this case. These representations are made to enable the Court to evaluate possible disqualification or recusal. (Use additional sheet if necessary.)

PARTY (List the names of all such parties and identify their connection and interest.)	**CONNECTION**
1. JACQUELINE HILL	1. INJURY PARTY, PLAINTIFF
2. MERCK CO., INC.	2. PHARMACEUTICAL COMPANY CAUSING INJURY, DEFENDANT

1/8/08
Date

Sign

GREGORY J. BULLIUNG, for JACQUELINE HILL
Attorney of record for or party appearing in pro per

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL PLAINTIFF(S) v. MERCK CO., INC. DEFENDANT(S).	CASE NUMBER SACV08-00065 AHS (ANx) **NOTICE OF** ☐ **Filing Fee Due on Pro Hac Vice Application** ☑ **Pro Hac Vice Application and Filing Fee Due**

To: Douglas M Schmidt, Ronald S Rash, Gregory J Bulliung

Please take notice that:

☐ Your *Pro Hac Vice* application, filed / lodged on _____ has been filed and granted by the court. As of today's date, the court has not yet received the application fee of $185.00. Please remit the fee and this notice immediately.

☑ Your *Pro Hac Vice* application has not been received by the court. Please return your completed application (form enclosed) along with the $185.00 fee and this notice immediately.

Please complete the **"Return"** portion of this form and return it and your fee in the form of a cashier's check, certified bank check, business or corporate check, government issued check, or money order drawn on a major America bank or the United States Postal Service, made checks payable to "U.S. District Court". The Clerk's Office will also accept credit cards (Mastercard/Visa, Discover, American Express) for filing fees and miscellaneous fees. Credit card payments may be made at all payment windows where receipts are issued. Mail fee and/or application to:

Clerk, U.S. District Court
Attn: Fiscal
312 N. Spring Street, Rm. G-8
Los Angeles, CA 90012

Clerk, U. S. District Court

JANUARY 25, 2008
Date

By K.L. GLOVER
Deputy Clerk

NOTE: ***The judge to whom this case is assigned will be notified if the fee, completed application or notification of active membership in the Central District of California or proof of payment is not received within thirty (30) days of the date of this notice.***

RETURN

Please check applicable box and return this notice with referenced documentation and/or fee.:

☐ I am currently an active member of the California State Bar and am enclosing an admission application for the United States District Court, Central District of California, and the fee instead of the *pro hac vice* application. Application for admission may be obtained from the court's website at **www.cacd.uscourts.gov**. Please include your California State Bar number on all subsequent documents filed (Local Rule 11-3.8).

☐ I am an active member of the bar for the United States District Court, Central District of California. My California State Bar number is _____. *(Note: Only if this section applies to you, please fax this to the Attorney Admission Clerk at (213) 894-2342).*

☐ My *pro hac vice* fee of $185.00 is enclosed.

☐ My *pro hac vice* application and fee are enclosed.

☐ My *pro hac vice* application is enclosed. The fee is not enclosed because I am an attorney for the United States, _____ *(please indicate the department or agency name).*

☐ My *pro hac vice* fee was previously paid. *(Please fax proof of payment to the Fiscal Section at (213) 894-4535.*

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

CIVIL MINUTES - GENERAL

Case No. SACV 08-65 AHS(ANx) Date: January 24, 2008

Title: JACQUELINE HILL v. MERCK & CO., INC.

PRESENT:

HONORABLE ALICEMARIE H. STOTLER, CHIEF U.S. DISTRICT JUDGE
(IN CHAMBERS)

Ellen Matheson	Not Present
Deputy Clerk	Court Reporter

ATTORNEYS PRESENT: None present

PROCEEDINGS: ORDER DIRECTING PLAINTIFF TO FILE A CORRECTED COMPLAINT NOT LATER THAN FEBRUARY 7, 2008

Plaintiff filed the Complaint in this action on January 18, 2008. Plaintiff has failed to comply with Local Rule 11-3.1.1 concerning the typeface size, Local Rule 11-3.3 concerning pagination, and Local rule 11-3.8 concerning title page. Accordingly, the Court orders plaintiff to file a corrected complaint not later than February 7, 2008.

The Clerk shall serve this minute order on all counsel of record in this action.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL, PLAINTIFF, v. MERCK CO., INC., DEFENDANT.	CASE NUMBER SACV 08-00065 AHS (ANx) ORDER TO REASSIGN CASE UPON RECUSAL MAGISTRATE JUDGE ☒ FOR DISCOVERY ☐ PER GENERAL ORDER 194

The undersigned Magistrate Judge to whom the above-entitled case was referred, being of the opinion that he should not hear said case pursuant to 28 USC §455(a), HEREBY ORDERS the case reassigned by the Clerk in accordance with section 3.2 of General Order 224.

IT IS FURTHER ORDERED that the Clerk serve copies of this order forthwith by first class mail on counsel for all parties appearing in this case.

DATED: January 24, 2008

/s/ ARTHUR NAKAZATO

ARTHUR NAKAZATO
UNITED STATES MAGISTRATE JUDGE

NOTICE TO COUNSEL FROM THE CLERK:

This case has been randomly referred to Magistrate Judge MARC C. GOLDMAN. On all documents subsequently filed in this case, substitute the initials MLG after the case number in place of the initials of the prior Magistrate Judge so that the case number will read as: SA CV 08-00065 AHS (MLGx)

This is very important because documents are routed to the Magistrate Judge by means of the initials.

Plaintiff's

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF DOCUMENT DISCREPANCIES

To: ☒ U.S. District Judge / ☐ U.S. Magistrate Judge AHS

From: Rolls Royce Paschal, Deputy Clerk Date Received: 2-1-08

Case No.: SACV 08-65 AHS (ANx) Case Title: Hill v. Merck

Document Entitled: Application of Non-Resident Atty to Appear in a Specific Case

Upon the submission of the attached document(s), it was noted that the following discrepancies exist:

☐	Local Rule 11-3.1	Document not legible
☐	Local Rule 11-3.8	Lacking name, address, phone and facsimile numbers
☐	Local Rule 11-4.1	No copy provided for judge
☐	Local Rule 19-1	Complaint/Petition includes more than ten (10) Does or fictitiously named parties
☐	Local Rule 15-1	Proposed amended pleading not under separate cover
☐	Local Rule 11-6	Memorandum/brief exceeds 25 pages
☐	Local Rule 11-8	Memorandum/brief exceeding 10 pages shall contain table of contents
☐	Local Rule 7.1-1	No Certification of Interested Parties and/or no copies
☐	Local Rule 6.1	Written notice of motion lacking or timeliness of notice incorrect
☐	Local Rule 56-1	Statement of uncontroverted facts and/or proposed judgment lacking
☐	Local Rule 56-2	Statement of genuine issues of material fact lacking
☐	Local Rule 7-19.1	Notice to other parties of ex parte application lacking
☐	Local Rule 16-6	Pretrial conference order not signed by all counsel
☐	FRCvP Rule 5(d)	No proof of service attached to document(s)
☒	Other:	Order Lacking - G.O. 07-08 Case is designated for E-filing [Proposed] Local Counsel must maintain an office in the Central District

Note: Please refer to the court's Internet website at www.cacd.uscourts.gov for local rules and applicable forms.

ORDER OF THE JUDGE/MAGISTRATE JUDGE

IT IS HEREBY ORDERED:

☐ The document is to be filed and processed. The filing date is ORDERED to be the date the document was stamped "received but not filed" with the Clerk. Counsel* is advised that any further failure to comply with the Local Rules may lead to penalties pursuant to Local Rule 83-7.

Date

U.S. District Judge / U.S. Magistrate Judge

☒ The document is **NOT** to be filed, but instead **REJECTED**, and is ORDERED returned to *counsel. *Counsel shall immediately notify, in writing, all parties previously served with the attached documents that said documents have **not** been filed with the Court.

FEB - 1 2008

Date

CHIEF U.S. District Judge ~~/ U.S. Magistrate Judge~~

ALICEMARIE H. STOTLER

*The term "counsel" as used herein also includes any pro se party. See Local Rule 1-3.

GPO U.S. GOVERNMENT PRINTING OFFICE: 2006-572-754/59178

Gregory J. Bulliung, Esq., CSB#144474
BULLIUNG & ASSOCIATES
5012 Mission Street
San Francisco, CA 94112
Telephone: (415) 841-9000
Facsimile: (415) 585-3300

Attorney for Plaintiff,
JACQUELINE HILL

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF
CALIFORNIA SOUTHERN DIVISION

JACQUELINE HILL, Plaintiff, vs. MERCK & CO., INC., Defendants.	Civil Action No. SACV08-65 AHS (MLGx) (CORRECTED) COMPLAINT FOR DAMAGES (Products Liability-Personal Injury) JURY TRIAL DEMANDED In re: FOSAMAX PRODUCTS LIABILITY LITIGATION

PLAINTIFF'S ORIGINAL COMPLAINT

Jacqueline Hill (hereinafter "Plaintiff"), by and through her undersigned counsel, sues Merck & Co., Inc., and states as follows:

1. This is a civil action brought on behalf of Plaintiff regarding personal injuries and damages that were a result of her ingestion of Fosamax® which was designed, manufactured, tested, marketed, distributed and sold to Plaintiff by Merck & Co., Inc. and/or its representatives.

I.

PARTIES

2. Plaintiff is a citizen and resident of the State of California, residing in Laguna Beach, California, County of Orange.

3. Defendant Merck & Co, Inc. (hereinafter "Defendant" or "Merck") is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100. Service of process may be accomplished by serving Merck & Co., Inc.'s Chief Financial Officer, Richard T. Clark, at Merck's principal office address of 1 Merck Dr., Whitehouse Station NJ 08889.

4. At all relevant times herein, Defendant, through its agents, servants and employees, was the designer, manufacturer, marketer, advertiser, distributor, and seller of the prescription

medication, Fosamax®, which is the brand name of alendronate sodium (hereinafter "Fosamax").

II.

JURISDICTION AND VENUE

5. Jurisdiction of this Court exists, pursuant to 28 U.S.C. § 1332, because Plaintiff is a citizen of a state other than the state in which the Defendant is incorporated and/or has its principal place of business, and the matter in controversy exceeds Seventy-five Thousand and no/100 dollars ($75,000.00), exclusive of interest and costs.

6. Venue is proper pursuant to 28 U.S.C. § 1391. Defendant has sufficient minimum contacts with California or otherwise intentionally avails itself of the consumer markets within California through the promotion, sale, marketing and/or distribution of its products in the State to render the exercise of jurisdiction by the California courts permissible under traditional notions of fair play and substantial justice.

7. This action includes claims for injuries to Jacqueline Hill caused by her ingestion of Fosamax and therefore should be, and Plaintiff consents to, transfer to Multidistrict Litigation No. 1789 In Re:

Fosamax Products Liability Litigation, United States District Court, Southern District of New York.

III.

CONDITIONS PRECEDENT

8. All conditions precedent have been performed or have occurred.

IV.

FACTUAL BACKGROUND

A. Fosamax Information

9. Fosamax was approved by the United States Food & Drug Administration ("FDA" herein) in September 1995. FDA-approved uses include the treatment of Paget's Disease and the prevention and treatment of osteoporosis.

10. Fosamax falls within a class of drugs known as bisphosphonates, which are used to treat bone conditions. Other drugs within this class, such as Aredia and Zometa, are also used as an adjunct to chemotherapy, but are not indicated for use in non-cancerous conditions such as osteoporosis.

11. There are two classes of bisphosphonates: nitrogenous (containing nitrogen) and non-nitrogenous (no nitrogen). Fosamax, Aredia, and Zometa are included in the nitrogenous bisphosphonates.

12. Fosamax is the world's top-selling bisphosphonate. It is Merck's second best-selling drug, with sales in 2005 of $3.2 billion, according to the Associated Press. In the U.S. alone, more than 22 million prescriptions were written last year, according to the drug research firm IMS Health.

B. Defendant's Failure to Warn of the Dangers of Fosamax

13. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent occurrence of osteonecrosis of the jaw ("ONJ" herein) in cancer patients using nitrogenous bisphosphonates, i.e., Aredia and Zometa. These drugs also have known gastrointestinal side effects which also occur with Fosamax. Defendant knew or should have known that Fosamax, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass.

14. Merck knew or should have known that bisphosphonates, including Fosamax, inhibit endothelial cell function; inhibit vascularization of the affected area; and induce ischemic changes to patients' lower and upper jaws (mandibles and maxillae) and that these ischemic changes appear to be cumulative in nature.

15. Merck also knew or should have known that these factors combine to create a compromised vascular supply

in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That, in turn, can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

16. Dentists are now being advised by dental associations to refrain from using invasive procedures (such as drilling a cavity) for any patient on Fosamax.

17. Shortly after Fosamax was released, the FDA began receiving reports of ONJ and other dental complications among Fosamax users, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates.

18. Despite this knowledge, Defendant failed to implement further studies regarding the risk of ONJ relative to Fosamax; Defendant proposed further uses of Fosamax, such as Fosamax-D; and sought to extend the exclusivity period of Fosamax through 2018.

19. ONJ is a serious medical event involving severe deterioration and decompensation of the jaw bones, is very difficult to treat once the patient is symptomatic, and can result in severe permanent disability and death.

20. By 2002 or earlier, Defendant knew or should have known that physician reports of Aredia patients suffering from ONJ showed a possible causal link between the use of ONJ and bisphosphonates.

21. Medical research published in 2004 revealed a link between ONJ and the use of bisphosphonates Aredia and Zometa. According to the report, "The jaw complications presented ... had a major negative effect on the quality of daily life for each of these patients" and "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," *Journal of Oral and Maxillofacial Surgery*, vol. 62, p. 533 (2004).

22. In September 2004 and May 2005, the manufacturer of bisphosphonates Aredia and Zometa sent warnings to health care professionals regarding the risk of ONJ associated with these drugs. Warnings were added to the Aredia and Zometa labels in August and November 2004, respectively.

23. On August 25, 2004, the FDA posted its Office of Drug Safety Postmarketing Safety Review on bisphosphonates (specifically Aredia, Zometa, Actonel, and Fosamax). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

24. Based on their review, the FDA observed that the risk of ONJ was not confined to bisphosphonates used for chemotherapy, but rather, was a class effect which

specifically extended to the oral bisphosphonate, Fosamax.

25. As a result, the FDA recommended and stated that Merck should amend the Fosamax labeling to specifically warn about the ONJ risk.

26. Merck has refused to accede to the FDA's request and to this day, the Fosamax labeling still contains no warning about the risk of ONJ.

27. Despite Defendant's knowledge about the increased risk of ONJ and other serious dental and oral complications in Fosamax patients, Defendant continues to defend Fosamax and minimize unfavorable findings rather than warn patients and the medical community.

C. Plaintiff's Use of Fosamax and Resulting Injury

28. Plaintiff used Fosamax as prescribed and in a foreseeable manner for the treatment or prevention of osteoporosis.

29. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of ONJ and other serious oral and dental conditions resulting from Fosamax use and would

have been able to avoid the clinical manifestation of the symptoms as they currently exist.

30. At all relevant times herein, there were safer alternative products available to consumers, including Plaintiff, to prevent and treat osteoporosis.

31. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking Fosamax.

32. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

33. As a direct and proximate result of using Fosamax, Plaintiff suffered severe jaw bone deterioration leading to osteonecrosis of the jaw.

V.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

34. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent

concealment and by the inherently undiscoverable nature of Plaintiff's injuries.

35. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her prescribing physicians the true risks associated with taking Fosamax. As a result of Defendant's actions, Plaintiff and her prescribing physicians, were unaware and/or could not have reasonably known or learned that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

36. Furthermore, Defendant is estopped from relying on any statute of limitations because of its fraudulent and/or intentional concealment of the true character, quality and nature of Fosamax. Defendant was under a duty to disclose the true character, quality and nature of Fosamax because this was non-public information over which the Defendant had and continues to have exclusive control, and because the Defendant knew that this information was not available to Plaintiff or her medical providers.

37. Plaintiff had no knowledge that Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment by Defendant, Plaintiff could not have reasonably discovered the wrongdoing at

any time prior. Also, the economics of this fraud should be considered. Defendant had the ability to spend and did spend enormous amounts of money in furtherance of its purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely solely on Defendant's representations.

38. Furthermore, the nature of Plaintiff's injuries and their relationship to Fosamax use was inherently undiscoverable. Consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff discovered, or by the exercise of reasonable diligence and intelligence should have discovered, that she had a basis for an actionable claim. Plaintiff did not have knowledge of facts that would lead a reasonable person to investigate and discover Defendant's tortious conduct. Under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

VI.

CAUSES OF ACTION

Count I:

Negligence

39. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

40. Defendant had a duty to exercise reasonable or ordinary care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax, including a duty to assure that consumers, like Plaintiff, did not suffer unreasonable adverse side effects, such as ONJ and a duty to warn consumers, including Plaintiff, of the serious risks associated with Fosamax use.

41. Defendant breached its legal duty by not exercising due care. Defendant knew or should have known that Fosamax created an unreasonable risk of ONJ and despite this knowledge, continued to market, distribute, and sell Fosamax to the public, including Plaintiff. Further, Defendant failed to conduct proper testing and failed to adequately warn and instruct consumers, including Plaintiff, about the risk of suffering serious harm from Fosamax use.

42. Defendant's conduct as described herein constitutes the violation of statutes, ordinances, and/or rules and regulations, including those promulgated by the FDA. Said statutes, ordinances, rules and regulations were designed to protect the health, safety, and welfare of the general public, including Plaintiff, from injuries such as those caused by Fosamax. Defendant had no excuse for its violative conduct and said conduct proximately caused Plaintiff's personal injuries complained of herein.

43. As a direct and proximate cause of Defendant's negligence in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax, Plaintiff has suffered and will continue to suffer injuries and monetary damages.

Count II:

Strict Liability - Design Defect

44. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

45. Fosamax *as* designed, manufactured and sold by Defendant was placed into the stream of commerce by Defendant in a defective and unreasonably dangerous

condition, taking into consideration the utility of the product and the risks involved with the drug's use.

46. Fosamax as designed, manufactured and sold by Defendant was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

47. Fosamax as designed, manufactured and sold by Defendant, was expected to reach and did reach consumers, including Plaintiff, without substantial change or alteration of the product.

48. Plaintiff used Fosamax as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant. However, Fosamax failed to perform safely.

49. Fosamax as designed, manufactured and sold by Defendant was defective due to inadequate testing.

50. As a direct, producing, and proximate result of the defective condition of Fosamax as designed, tested, developed, manufactured, marketed, and sold by Defendant, Plaintiff has suffered and will continue to suffer injuries and monetary damages.

////

Count III:

Strict Liability - Failure to Warn

51. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

52. Defendant's marketing of Fosamax was defective because Defendant failed to give adequate warnings of the dangers of Fosamax that were known or should have been known by Defendant, including ONJ; and/or because Defendant failed to give adequate instructions to avoid such dangers, which failure rendered Fosamax unreasonably dangerous as marketed.

53. As a direct, producing, and proximate result of Defendant's failure to properly warn physicians and consumers, Plaintiff has suffered and will continue to suffer injuries and monetary damages.

Count IV:

Breach of Express Warranty

54. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

55. Defendant expressly warranted, by and through statements made by Defendant or its authorized agents, that Fosamax was safe, effective, and fit for its intended use.

56. Plaintiff and her physicians relied on the skill, judgment and representations of Defendant.

57. Fosamax did not conform to Defendant's express warranties in that it was not safe and fit for its intended use because it caused serious and permanent adverse side effects, including ONJ.

58. As a direct and proximate result of Defendant's breach of its express warranties, Plaintiff has suffered and will continue to suffer injuries and monetary damages.

Count V:

Breach of Implied Warranty

59. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

60. Defendant impliedly warranted to Plaintiff and her physicians that Fosamax was of merchantable quality and was safe and fit for its intended use.

61. Plaintiff and her physicians relied on Defendant's skill and judgment.

62. Fosamax was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including ONJ.

63. As a direct and proximate result of Defendant's breach of its implied warranties, Plaintiff was caused to suffer and will continue to suffer injuries and monetary damages.

Count VI:

Deceptive Trade Practices

64. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

65. Defendant engaged in commercial conduct by selling Fosamax.

66. Defendant misrepresented, omitted, and/or concealed material information regarding Fosamax by failing to disclose known risks. Defendant engaged in unfair, unconscionable, deceptive and/or fraudulent acts or practices when it failed to adequately warn consumers and the medical community of the safety risks associated with Fosamax. By failing to disclose the known dangers

and risks of Fosamax, Defendant engaged in unfair and deceptive consumer-oriented acts.

67. Reasonable consumers, including Plaintiff, were injured by Defendant's unfair and deceptive acts and/or practices. As a direct and proximate result of Defendant's deceptive, unfair, unconscionable and fraudulent conduct, Plaintiff has suffered and will continue to suffer personal injuries and economic damages.

68. Furthermore, Defendant's conduct was committed knowingly, willfully, and/or intentionally, thereby entitling Plaintiff to three times the actual damages sustained and such other relief as the court considers necessary and proper, in accordance with the applicable law.

Count VII:

Fraudulent Misrepresentation

69. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

70. Defendant, in the course of its business, fraudulently represented to the medical community and to Plaintiff and the general public that Fosamax had

been adequately tested and was a safe and effective drug. Said representation was material and was false.

71. At the time, Defendant knew said representation was false, or made said representation recklessly, as a positive assertion, and without knowledge of its truth. Defendant knew or should have known that Fosamax had not been adequately tested, was defective in nature, and did not carry adequate warnings and instructions.

72. Defendant made said representations with the intent of defrauding and deceiving the general public, Plaintiff, and the medical community so as to increase sales of Fosamax. This shows Defendant's callous and reckless indifference to the health, safety, and welfare of Plaintiff and the general public.

73. Plaintiff reasonably relied on Defendant's false representations in choosing to ingest Fosamax.

74. As a result of Defendant's fraudulent representations, Plaintiff has suffered and will continue to suffer from serious personal injuries and monetary losses.

////

Count VIII:

Negligent Misrepresentation

75. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

76. Defendant, in the course of its business, made false representations to the medical community, and to Plaintiff and the public in general, that Fosamax was a safe and effective drug.

77. Defendant, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Fosamax, in that it made such misrepresentations when it knew, or reasonably should have known, of the falsity of such representations. Alternatively, Defendant made such misrepresentations without exercising due care to ascertain the accuracy of said representations.

78. Defendant supplied false information for the guidance of others. Defendant, through its misrepresentations, intended to induce reliance by Plaintiff, other consumers, and the medical community.

79. Plaintiff and her physicians justifiably relied on Defendant's misrepresentations.

80. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has suffered and will continue to suffer injuries and monetary losses.

Count IX:

Fraud and Deceit

81. Defendant conducted research and used the drug Fosamax as part of their research.

82. As a result of Defendant's research and testing, or lack thereof, Defendant distributed blatantly and intentionally false information including, but not limited to, assuring the public, Plaintiff, the medical community, and/or the FDA that Fosamax was safe to use for the treatment and prevention of osteoporosis.

83. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, Plaintiff, the medical community, and/or the FDA.

84. Defendant had a duty to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff, the medical community or the FDA.

85. The information distributed by Defendant to the public, Plaintiff, the medical community, and/or the FDA included, but was not limited to, reports and press

releases and contained material representations of fact and/or admissions.

86. The information distributed by Defendant to the public, Plaintiff, the medical community and/or the FDA intentionally included representations that Fosamax was safe to treat and prevent osteoporosis and was not injurious to the health and/or safety of its intended users.

87. Said representations were material, false and misleading.

88. Defendant knew said representations were false.

89. Upon information and belief, Defendant intentionally suppressed, ignored, and disregarded test results not favorable to the Defendant, and results that demonstrated that Fosamax was not safe as a means to treat and prevent osteoporosis.

90. In making the foregoing false representations, Defendant intended to deceive and defraud the public, Plaintiff, the medical community, and the FDA; to gain their confidence by
falsely ensuring that Fosamax was safe and fit for its intended use; and to
induce the public, including Plaintiff to use Fosamax.

91. Defendant made claims and representations in its documents submitted to the FDA, the public, and

Plaintiff that Fosamax did not present serious health and/or safety risks.

92. When Defendant made the false representations described herein, Defendant knew said representations were false.

93. Defendant willfully and intentionally failed to disclose material facts regarding the dangerous and serious safety concerns of Fosamax by concealing and suppressing said facts.

94. Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts, and made false representations with the purpose and design of deceiving and lulling Plaintiff into a sense of security so that Plaintiff would rely on the representations and purchase, use, and rely on Fosamax and/or that her health care providers would do the same.

95. Plaintiff believed Defendant's representations to be true at the time they were made and reasonably relied on said representations.

96. At the time the representations were made, Plaintiff did not know the truth and could not have discovered the truth using due diligence, regarding the dangerous and serious health and/or safety concerns of Fosamax.

97. Defendant's aforementioned conduct constitutes fraud and deceit and was committed and/or perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

98. As a result of Defendant's foregoing acts and omissions, Plaintiff has suffered and will continue to suffer personal injuries and monetary losses.

VII.

DAMAGES

A. Compensatory Damages

99. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

100. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff suffered from severe jaw bone deterioration leading to ONJ, a painful disfiguring irreversible condition that now increases her personal risk for other dental complications, severe disability and death. As a result, Plaintiff suffers from mental anguish and diminished enjoyment of life. Further, she has incurred and will continue to incur medical costs for oral and maxillofacial care, including but not limited to hospitalizations, prescription medications, medical care, and treatment supplies. Plaintiff has already undergone two surgeries to remove

both the left and right mandibular torus where the necrotic or dead jaw bone had separated itself from the normal bone. Her condition has caused and will continue to cause severe pain and disfigurement.

101. Additionally, Plaintiff has suffered from loss of earnings and/or a diminution in earning capacity as a direct and proximate result of Defendant's foregoing wrongful conduct.

102. Plaintiff gives notice to Defendant that she is suing for past, present and future damages with respect to each element set out herein. Plaintiff pleads for pre-judgment interest and post-judgment interest as provided by law. Plaintiff expressly reserves the right to amend this Petition to plead an increase in damages sought herein.

103. Plaintiff is entitled to, and seeks herein, the following elements of damage experienced in the past:

a. Physical pain and suffering;

b. Mental or emotional pain and suffering / mental anguish;

c. Loss of capacity for the enjoyment of life / diminished quality of life / physical impairment;

d. Reasonable and necessary expenses for medical care, services, and supplies actually given in the treatment of Plaintiff as shown by the evidence;

e. Loss of earning capacity, including, but not limited to, actual loss of income, if any; and

f. Disfigurement.

104. Plaintiff is further entitled to, and seeks herein, compensation for the present cash value of the following elements of damage reasonably certain to be experienced by Plaintiff in the future:

a. Physical pain and suffering;

b. Mental or emotional pain and suffering / mental anguish;

c. Loss of capacity for the enjoyment of life / diminished quality of life / physical impairment;

d. Medical expenses reasonably certain to be required in the future;

e. Loss of earning capacity, if any; and

f. Disfigurement.

B. Punitive Damages

105. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

106. Defendant's conduct complained of herein was malicious, intentional, outrageous, reckless, done with bad motives, and/or in wanton, willful, conscious, and/or deliberate disregard of Plaintiff's rights and safety. Defendant's conduct was committed with a reckless indifference to the interest of others, including

Plaintiff, the consuming public, health care professionals and the FDA.

107. At all times relevant hereto, Defendant actually knew of the defective nature of Fosamax, as set forth herein, and continued to design, manufacture, market, distribute, and sell Fosamax so as to maximize sales and profits at the expense of the public's health and safety and in wanton and willful disregard of the foreseeable serious harm caused by Fosamax. Defendant's conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, maliciousness, recklessness, and/or wanton and willful disregard for the safety and rights of Plaintiff, as well as the general public and/or consumers of Fosamax.

108. As a direct and proximate result of Defendant's conduct set out herein, Plaintiff suffered harm and is therefore entitled to punitive damages so as to punish Defendant and to deter similar conduct in the future.

C. Treble Damages

109. Defendant is liable for treble damages under the consumer protection statutes. Defendant engaged in deceptive, unfair, misleading, unconscionable and/or fraudulent conduct in violation of consumer protection statutes. Defendant's conduct was committed knowingly,

willfully, and/or intentionally within the meaning of such terms as defined in said statutes.

110. Therefore, Plaintiff is entitled to and will seek three times the actual damages sustained and such other relief as the court considers necessary and proper, in accordance with the applicable law.

VIII.

DEMAND FOR JURY TRIAL

111. Plaintiff hereby demands trial by jury in this action of all issues so triable.

IX.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff requests that Defendant be cited to appear and answer herein and that upon final trial of this cause Plaintiff have judgment against Defendant for compensatory, punitive and/or treble damages as awarded by the jury plus interest, prejudgment and post-judgment, reasonable attorneys' fees, filing fees and reasonable costs of court as provided by law, and, for such other and further legal and equitable relief as this Honorable Court deems just and proper.

////

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFF

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JAQUELINE HILL

Plaintiff(s)

v.

MERCK CO., INC.

Defendant(s).

CASE NUMBER

SACV08-00065 AHS(MLGx)

ORDER ON APPLICATION OF NON-RESIDENT ATTORNEY TO APPEAR IN A SPECIFIC CASE

The Court, having reviewed the accompanying Application of Douglas Schmidt
Applicant's Name

of Douglas M. Schmidt APLC 335 City Park Ave. New Orleans, Louisiana 70119
Firm Name / Address

(504)482-5711
Telephone Number

dglsschmdt@yahoo.com
E-mail Address

for permission to appear and participate in the above-entitled action on behalf of ☑ Plaintiff ☐ Defendant

Jacqueline Hill

and the designation of Gregory Bulliung 144474
Local Counsel Designee /State Bar Number

of Bulliung & Associates 5012 Mission St. San Francisco, CA 94112
Local Counsel Firm / Address

(415)841-9000
Telephone Number

(415)585-3300
E-mail Address

as local counsel, hereby **ORDERS** the Application be:

☐ GRANTED

☒ DENIED. Fee, if paid, shall be returned by the Clerk.

Dated FEB - 8 2008

CHIEF U. S. District Judge ~~U.S. Magistrate Judge~~

VENABLE LLP
DOUGLAS C. EMHOFF (Cal. Bar No. 151049)
JEFFREY M. TANZER (Cal. Bar No. 129437)
2049 Century Park East, Suite 2100
Los Angeles, California 90067
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Facsimile: (310) 229-9901

Attorneys for Defendant
MERCK & CO., INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL, Plaintiff, vs. MERCK & CO., INC., Defendant.	CASE NO. SACV08-0065 AHS (MLGx) **DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT** **DEMAND FOR JURY TRIAL**

VENABLE LLP
2049 CENTURY PARK EAST, #2100
LOS ANGELES, CALIFORNIA 90067
(310) 229-9900

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers Plaintiffs' Complaint ("Complaint"). Merck denies all allegations set forth in the Complaint directed at Merck except to the extent such allegations are specifically admitted below:

1. Merck denies each and every allegation of Paragraph 1, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck further admits that Plaintiff purports to bring a civil action for damages, but denies that there is any factual or legal basis for same. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 1.

I.

PARTIES

2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 2.

3. Merck admits the allegations of the first sentence of Paragraph 3. Merck denies the allegations of the second sentence of Paragraph 3.

4. Merck denies each and every allegation of Paragraph 4, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

II.

JURISDICTION AND VENUE

5. The allegations of Paragraph 5 are conclusions of law to which no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 5, except for jurisdictional purposes only, admits that Plaintiff seeks in excess of $75,000.

6. The allegations of Paragraph 6 are conclusions of law to which no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 6.

7. The allegations of Paragraph 7 do not contain factual allegations to which Merck must respond. To the extent a response is required, Merck denies each and every allegation of Paragraph 7, except concurs that this case should be made part of MDL 1789.

III.

CONDITIONS PRECEDENT

8. Merck denies each and every allegation of Paragraph 8.

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IV.

FACTUAL BACKGROUND

A. Fosamax Information

9. Merck denies each and every allegation of Paragraph 9, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 9 inconsistent with that prescribing information.

10. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 10 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 10 with respect to Aredia and Zometa inconsistent with that prescribing information.

11. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 11 inconsistent with that prescribing information. Merck respectfully refers the Court to the Physician's Desk Reference ("PDR") for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 11 with respect to Aredia and Zometa inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 11.

12. Merck denies each and every allegation of Paragraph 12, except that Merck admits that Fosamax product sales in 2005 amounted to approximately $3.19 billion.

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B. Defendant's Failure to Warn of the Dangers of Fosamax

13. Merck denies each and every allegation of Paragraph 13.

14. Merck denies each and every allegation of Paragraph 14.

15. Merck denies each and every allegation of Paragraph 15.

16. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 16.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 21, except that it admits that Ruggiero, et al., published an article entitled, "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004) and respectfully refers the Court to said article for its actual language and full text.

22. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29.

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30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

V.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

34. Merck denies each and every allegation of Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

VI.

CAUSES OF ACTION

Count I:

Negligence

39. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

40. The allegations in Paragraph 40 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

Count II:

Strict Liability – Design Defect

44. Merck repleads its answers to each and every paragraph contained in the

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Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

45. Merck denies each and every allegation of Paragraph 45, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

48. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first sentence of Paragraph 48. Merck denies each and every allegation of the second sentence of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

Count III:

Strict Liability – Failure to Warn

51. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

Count IV:

Breach of Express Warranty

54. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

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55. Merck denies each and every allegation of Paragraph 55, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

56. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

Count V:

Breach of Implied Warranty

59. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

60. Merck denies each and every allegation of Paragraph 60, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

61. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

Count VI:

Deceptive Trade Practices

64. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

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65. Merck is without knowledge as to what is meant by the phrase "commercial conduct," so the allegations in Paragraph 65 are denied.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

Count VII:

Fraudulent Misrepresentation

69. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

Count VIII:

Negligent Misrepresentation

75. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

80. Merck denies each and every allegation of Paragraph 80.

Count IX:

Fraud and Deceit

81. Merck is without knowledge as to what is meant by the term "research," so

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the allegations in Paragraph 81 are denied.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. The allegations in Paragraph 84 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

85. Merck denies each and every allegation of Paragraph 85, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

86. Merck denies each and every allegation of Paragraph 86, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

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VII.

DAMAGES

A. Compensatory Damages

99. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

100. Merck denies each and every allegation of Paragraph 100, except that Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the fourth sentence of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. The allegations of Paragraph 102 do not require a response.

103. Merck denies each and every allegation of Paragraph 103, including each and every allegation contained in subparts (a) through (f).

104. Merck denies each and every allegation of Paragraph 104, including each and every allegation contained in subparts (a) through (f).

B. Punitive Damages

105. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

106. Merck denies each and every allegation of Paragraph 106.

107. Merck denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

109. Merck denies each and every allegation of Paragraph 109.

110. Merck denies each and every allegation of Paragraph 110.

VIII.

DEMAND FOR JURY TRIAL

111. The allegations of Paragraph 111 do not require a response.

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IX.

PRAYER FOR RELIEF

Merck denies that Plaintiff is entitled to any of the relief requested in her Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

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FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were cause in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

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ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

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EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

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TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States and the Constitution of California.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by this Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the

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product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claimed are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

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THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens.*

FORTIETH AFFIRMATIVE DEFENSE

If Plaintiff have sustained injury or loss as alleged in the Complaint, such injury or loss may have been caused by parties other than answering defendant, or third persons not parties to this action, who may have been negligent, legally responsible, or otherwise at fault. In the event of a finding of liability in favor of Plaintiff, a settlement, or a judgment against answering defendant, answering defendant requests an apportionment of fault among all parties and third persons as permitted by *Li v. Yellow Cab Company* and *America Motorcycle Association v. Superior Court.* Answering defendant also requests a judgment and declaration of partial indemnification and contribution against all other parties or third persons in accordance with the apportionment of fault.

FORTY-FIRST AFFIRMATIVE DEFENSE

The asymptomatic plaintiff lacks standing because they have suffered no damages and no injury-in-fact.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and

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compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

PRAYER FOR RELIEF

WHEREFORE, Merck prays as follows:

1. That Plaintiffs take nothing by the Complaint;

2. That this action be dismissed with prejudice;

3. That Merck be awarded its costs of suit herein, and its attorney's fees to the extent provided for by statute or contract;

4. For such other and further relief as the Court deems just and proper.

Dated: February 13, 2008

VENABLE LLP
DOUGLAS C. EMHOFF
JEFFREY M. TANZER

By /s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer
Attorneys for Defendant
Merck & Co., Inc.

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DEMAND FOR JURY TRIAL

Merck demands a trial by jury as to all issues so triable.

Dated: February 13, 2008

VENABLE LLP
DOUGLAS C. EMHOFF
JEFFREY M. TANZER

By /s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer
Attorneys for Defendant
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PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 2049 Century Park East, #2100, Los Angeles, California 90067.

On February 13, 2008, I served the foregoing document(s) described as **DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT; DEMAND FOR JURY TRIAL** on the interested parties in this action addressed as follows:

SEE ATTACHED SERVICE LIST

☒ By placing true copies thereof enclosed in a sealed envelope(s) addressed as stated above.

☐ **BY PERSONAL SERVICE (CCP §1011)**: I delivered such envelope(s) by hand to the addressee(s) as stated above.

☒ **BY MAIL (CCP §1013(a)&(b))**: I am readily familiar with the firm's practice of collection and processing correspondence for mailing with the U.S. Postal Service. Under that practice such envelope(s) is deposited with the U.S. postal service on the same day this declaration was executed, with postage thereon fully prepaid at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

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Executed on February 13, 2008, at Los Angeles, California

☐ **(STATE)** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

☒ **(FEDERAL)** I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.

/s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer

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Attorneys for Defendant
MERCK & CO., INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL,

Plaintiff,

vs.

MERCK & CO., INC.,

Defendant.

CASE NO. SACV08-0065 AHS (MLGx)

DEFENDANT MERCK & CO., INC.'S NOTICE OF RELATED CASES AND NOTICE OF PENDENCY OF OTHER PROCEEDINGS

[Local Rules 83-1.3 and 83-1.4]

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TO THE COURT, AND TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that, pursuant to Local Rule 83-1.3, Defendant Merck & Co., Inc. ("Merck") hereby gives notice of 17 related cases in the United States District Court for the Central District of California, entitled *Karen Johnson v. Merck & Co., Inc.*, Case No. CV 06-5378 FMC (PJWx), *Edward A. Morris, et al. v. Merck & Co., Inc. et al.*, Case No. CV 06-5587 FMC (PJWx), *Anne E. Clayton v. Merck & Co., Inc., et al.*, Case No. CV 06-6398 FMC (PJWx), *Valiente v. Merck & Co., Inc., et al.*, Case No. CV 06-7027 FMC (PJWx), *Hammond v. Merck & Co., Inc.*, Case No. CV 06-7343 FMC (PJWx), *Ferraro, et al. v. Merck & Co., et al,*, No. CV 06-7733 (FMC)

(PJWx), *Demsky, et al. v. Merck & Co., et al.*, No. CV 07-2839 (FMC) (PJWx), *Bujdoso, et al., v. Merck & Co., et al.*, Case No. CV 07-3490 (FMC) (PJWx), *Finch, et al., v. Merck & Co., et al.*, Case No. CV 07-3492 (FMC) (PJWx), *Horton, et al., v. Merck & Co., et al.*, Case No. CV 07-3493 (FMC) (PJWx), *Martin, et al., v. Merck & Co., et. al.*, Case No. CV 07-3495 (FMC) (PJWx), *Cecilia Smith, et al., v. Merck & Co., et al.*, Case No. CV 07-3497 (FMC) (PJWx), Evans, *et al., v. Merck & Co., et al.*, Case No. CV 07-4136 (FMC) (PJWx), *Goss, et al., v. Merck & Co., et al.*, Case No. CV 07-4172 (FMC) (PJWx), *Vasquez, et al., v. Merck & Co., et al.*, Case No. CV 07-4326 (FMC) (PJWx), *Moyer, et al., v. Merck & Co., et al.*, Case No. CV 07-4651 (FMC) (PJWx), and *Carrie Smith, et al., v. Merck & Co., et al.*, Case No. CV 07-4655 (FMC) PJWx).

These cases, like the above-captioned action, involve allegations regarding the prescription medication FOSAMAX® and will therefore call for the determination of the same or substantially related or similar questions of law and fact, and would entail substantial duplication of labor if heard by different judges. All 18 cases, including the above-captioned action, contain essentially the same allegations that certain injuries were caused by the prescription medication FOSAMAX®, and having all of these matters assigned to a single judge is appropriate.

PLEASE TAKE FURTHER NOTICE that, pursuant to Local Rule 83-1.4, Merck hereby gives notice that the above-captioned case is the subject of or is related to Multidistrict Litigation that is pending in the United Stated District Court for the Southern District of New York, encaptioned In re Fosamax Products Liability Litigation, MDL-1789. On August 16, 2006, the Judicial Panel on Multidistrict Litigation ("MDL Panel") issued an order transferring 18 FOSAMAX® products liability cases to the United States District Court for the Southern District of New York (Keenan, J.) for coordinated pretrial proceedings under 28 U.S.C. § 1407. *In re Fosamax Products Liability Litigation*, MDL No. 1789. To date, the MDL Panel has

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issued 47 Conditional Transfer Orders, at least 131 cases involving FOSAMAX® have been transferred to MDL-1789, and there are a total of 371 cases pending in the MDL, including cases filed directly in the Southern District of New York.

All of the cases identified in the first paragraph above, which were filed in this District and were assigned to and/or related to the Honorable Florence-Marie Cooper, have previously been transferred from this District to the MDL. [1]

Merck will seek the transfer of this action to MDL-1789, and will, in the next several days, provide the MDL Panel with notice of this action pursuant to the "tag-along" procedure contained in the MDL Rules.

Dated: February 13, 2008

VENABLE LLP
DOUGLAS C. EMHOFF
JEFFREY M. TANZER

By /s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer
Attorneys for Defendant
Merck & Co., Inc.

[1] Pursuant to a stipulation of the parties, the case of *Johnson v. Merck* was dismissed without prejudice by Judge Keenan in the United States District Court for the Southern District of New York, after a transfer of that case to MDL No. 1789.

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PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 2049 Century Park East, #2100, Los Angeles, California 90067.

On February 13, 2008, I served the foregoing document(s) described as **DEFENDANT MERCK & CO., INC.'S NOTICE OF RELATED CASES AND NOTICE OF PENDENCY OF OTHER PROCEEDINGS** on the interested parties in this action addressed as follows:
SEE ATTACHED SERVICE LIST

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Executed on February 13, 2008, at Los Angeles, California

☐ **(STATE)** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

☒ **(FEDERAL)** I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.

/s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer

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NAME, ADDRESS & TELEPHONE NUMBER OF ATTORNEY(S) FOR, OR, PLAINTIFF OR DEFENDANT IF PLAINTIFF OR DEFENDANT IS PRO PER

Douglas C. Emhoff
Jeffrey M. Tanzer
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ATTORNEYS FOR: Defendant, MERCK & CO., INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL Plaintiff(s), v. MERCK & CO., INC. Defendant(s)	CASE NUMBER SACV08-0065 AHS (MLGx) **CERTIFICATION AND NOTICE OF INTERESTED PARTIES (Local Rule 7.1-1)**

TO: THE COURT AND ALL PARTIES APPEARING OF RECORD:

The undersigned, counsel of record for Defendant, MERCK & CO., INC. (or party appearing in pro per), certifies that the following listed party (or parties) has (have) a direct, pecuniary interest in the outcome of this case. These representations are made to enable the Court to evaluate possible disqualification or recusal. (Use additional sheet if necessary.)

PARTY (List the names of all such parties and identify their connection and interest.)	CONNECTION
JACQUELINE HILL	PLAINTIFF
MERCK & CO., INC.	DEFENDANT

February 13, 2008
Date

Sign:
Jeffrey M. Tanzer

Attorney of record for or party appearing in pro per
Defendant, MERCK & CO., INC.

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 2049 Century Park East, #2100, Los Angeles, California 90067.

On February 13, 2008, I served the foregoing document(s) described as **CERTIFICATION AND NOTICE OF INTERESTED PARTIES** on the interested parties in this action addressed as follows:
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Executed on February 13, 2008, at Los Angeles, California

☐ **(STATE)** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

☒ **(FEDERAL)** I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.

/s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer

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Attorneys for Defendant
MERCK & CO., INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL, Plaintiff, vs. MERCK & CO., INC., Defendant.	CASE NO. SACV08-0065 AHS (MLGx) **DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT** **DEMAND FOR JURY TRIAL**

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers Plaintiffs' Complaint ("Complaint"). Merck denies all allegations set forth in the Complaint directed at Merck except to the extent such allegations are specifically admitted below:

1. Merck denies each and every allegation of Paragraph 1, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in

accordance with its approved prescribing information. Merck further admits that Plaintiff purports to bring a civil action for damages, but denies that there is any factual or legal basis for same. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 1.

I.

PARTIES

2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 2.

3. Merck admits the allegations of the first sentence of Paragraph 3. Merck denies the allegations of the second sentence of Paragraph 3.

4. Merck denies each and every allegation of Paragraph 4, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

II.

JURISDICTION AND VENUE

5. The allegations of Paragraph 5 are conclusions of law to which no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 5, except for jurisdictional purposes only, admits that Plaintiff seeks in excess of $75,000.

6. The allegations of Paragraph 6 are conclusions of law to which no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 6.

7. The allegations of Paragraph 7 do not contain factual allegations to which Merck must respond. To the extent a response is

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required, Merck denies each and every allegation of Paragraph 7, except concurs that this case should be made part of MDL 1789.

III.
CONDITIONS PRECEDENT

8. Merck denies each and every allegation of Paragraph 8.

IV.
FACTUAL BACKGROUND

A. Fosamax Information

9. Merck denies each and every allegation of Paragraph 9, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 9 inconsistent with that prescribing information.

10. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 10 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 10 with respect to Aredia and Zometa inconsistent with that prescribing information.

11. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 11 inconsistent with that prescribing information. Merck respectfully refers the Court to the Physician's Desk Reference ("PDR")

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for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 11 with respect to Aredia and Zometa inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 11.

12. Merck denies each and every allegation of Paragraph 12, except that Merck admits that Fosamax product sales in 2005 amounted to approximately $3.19 billion.

B. Defendant's Failure to Warn of the Dangers of Fosamax

13. Merck denies each and every allegation of Paragraph 13.

14. Merck denies each and every allegation of Paragraph 14.

15. Merck denies each and every allegation of Paragraph 15.

16. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 16.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 21, except that it admits that Ruggiero, et al., published an article entitled, "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004) and respectfully refers the Court to said article for its actual language and full text.

22. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23,

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except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

V.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

34. Merck denies each and every allegation of Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

VI.

CAUSES OF ACTION

Count I:

Negligence

39. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates

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the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

40. The allegations in Paragraph 40 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

Count II:

Strict Liability – Design Defect

44. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

45. Merck denies each and every allegation of Paragraph 45, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

48. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first sentence of

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Paragraph 48. Merck denies each and every allegation of the second sentence of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

Count III:

Strict Liability – Failure to Warn

51. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

Count IV:

Breach of Express Warranty

54. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

55. Merck denies each and every allegation of Paragraph 55, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

56. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

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Count V:
Breach of Implied Warranty

59. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

60. Merck denies each and every allegation of Paragraph 60, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

61. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

Count VI:
Deceptive Trade Practices

64. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

65. Merck is without knowledge as to what is meant by the phrase "commercial conduct," so the allegations in Paragraph 65 are denied.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

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Count VII:
Fraudulent Misrepresentation

69. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

Count VIII:
Negligent Misrepresentation

75. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

80. Merck denies each and every allegation of Paragraph 80.

Count IX:
Fraud and Deceit

81. Merck is without knowledge as to what is meant by the term "research," so the allegations in Paragraph 81 are denied.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

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84. The allegations in Paragraph 84 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

85. Merck denies each and every allegation of Paragraph 85, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

86. Merck denies each and every allegation of Paragraph 86, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

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VII.
DAMAGES

A. Compensatory Damages

99. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

100. Merck denies each and every allegation of Paragraph 100, except that Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the fourth sentence of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. The allegations of Paragraph 102 do not require a response.

103. Merck denies each and every allegation of Paragraph 103, including each and every allegation contained in subparts (a) through (f).

104. Merck denies each and every allegation of Paragraph 104, including each and every allegation contained in subparts (a) through (f).

B. Punitive Damages

105. Merck repleads its answers to each and every paragraph contained in the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

106. Merck denies each and every allegation of Paragraph 106.

107. Merck denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

109. Merck denies each and every allegation of Paragraph 109.

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110. Merck denies each and every allegation of Paragraph 110.

VIII.
DEMAND FOR JURY TRIAL

111. The allegations of Paragraph 111 do not require a response.

IX.
PRAYER FOR RELIEF

Merck denies that Plaintiff is entitled to any of the relief requested in her Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

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THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

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NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

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FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck

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provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly

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authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States and the Constitution of California.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by this Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable

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and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claimed are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens.*

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FORTIETH AFFIRMATIVE DEFENSE

If Plaintiff have sustained injury or loss as alleged in the Complaint, such injury or loss may have been caused by parties other than answering defendant, or third persons not parties to this action, who may have been negligent, legally responsible, or otherwise at fault. In the event of a finding of liability in favor of Plaintiff, a settlement, or a judgment against answering defendant, answering defendant requests an apportionment of fault among all parties and third persons as permitted by *Li v. Yellow Cab Company* and *America Motorcycle Association v. Superior Court*. Answering defendant also requests a judgment and declaration of partial indemnification and contribution against all other parties or third persons in accordance with the apportionment of fault.

FORTY-FIRST AFFIRMATIVE DEFENSE

The asymptomatic plaintiff lacks standing because they have suffered no damages and no injury-in-fact.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

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FORTY-FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

PRAYER FOR RELIEF

WHEREFORE, Merck prays as follows:

1. That Plaintiffs take nothing by the Complaint;

2. That this action be dismissed with prejudice;

3. That Merck be awarded its costs of suit herein, and its attorney's fees to the extent provided for by statute or contract;

4. For such other and further relief as the Court deems just and proper.

Dated: February 20, 2008

VENABLE LLP
DOUGLAS C. EMHOFF
JEFFREY M. TANZER

By /s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer
Attorneys for Defendant
Merck & Co., Inc.

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DEMAND FOR JURY TRIAL

Merck demands a trial by jury as to all issues so triable.

Dated: February 20, 2008

VENABLE LLP
DOUGLAS C. EMHOFF
JEFFREY M. TANZER

By /s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer
Attorneys for Defendant
Merck & Co., Inc.

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PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 2049 Century Park East, #2100, Los Angeles, California 90067.

On February 20, 2008, I served the foregoing document(s) described as **DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT; DEMAND FOR JURY TRIAL** on the interested parties in this action addressed as follows:

SEE ATTACHED SERVICE LIST

☒ By placing true copies thereof enclosed in a sealed envelope(s) addressed as stated above.

☐ **BY PERSONAL SERVICE (CCP §1011)**: I delivered such envelope(s) by hand to the addressee(s) as stated above.

☒ **BY MAIL (CCP §1013(a)&(b))**: I am readily familiar with the firm's practice of collection and processing correspondence for mailing with the U.S. Postal Service. Under that practice such envelope(s) is deposited with the U.S. postal service on the same day this declaration was executed, with postage thereon fully prepaid at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY (CCP §1013(c)&(d))**: I am readily familiar with the firm's practice of collection and processing items for delivery with Overnight Delivery. Under that practice such envelope(s) is deposited at a facility regularly maintained by Overnight Delivery or delivered to an authorized courier or driver authorized by Overnight Delivery to receive such envelope(s), on the same day this declaration was executed, with delivery fees fully provided for at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

Executed on February 20, 2008, at Los Angeles, California

☐ **(STATE)** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

☒ **(FEDERAL)** I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.

/s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer

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Attorneys for Defendant
MERCK & CO., INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JACQUELINE HILL,

Plaintiff,

vs.

MERCK & CO., INC.,

Defendant.

CASE NO. SACV08-0065 AHS (MLGx)

DEFENDANT MERCK & CO., INC.'S NOTICE OF RELATED CASES AND NOTICE OF PENDENCY OF OTHER PROCEEDINGS

[Local Rules 83-1.3 and 83-1.4]

TO THE COURT, AND TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that, pursuant to Local Rule 83-1.3, Defendant Merck & Co., Inc. ("Merck") hereby gives notice of 17 related cases in the United States District Court for the Central District of California, entitled *Karen Johnson v. Merck & Co., Inc.*, Case No.

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CV 06-5378 FMC (PJWx), *Edward A. Morris, et al. v. Merck & Co., Inc. et al.*, Case No. CV 06-5587 FMC (PJWx), *Anne E. Clayton v. Merck & Co., Inc., et al.*, Case No. CV 06-6398 FMC (PJWx), *Valiente v. Merck & Co., Inc., et al.*, Case No. CV 06-7027 FMC (PJWx), *Hammond v. Merck & Co., Inc.*, Case No. CV 06-7343 FMC (PJWx), *Ferraro, et al. v. Merck & Co., et al,*, No. CV 06-7733 (FMC) (PJWx), *Demsky, et al. v. Merck & Co., et al.*, No. CV 07-2839 (FMC) (PJWx), *Bujdoso, et al., v. Merck & Co., et al.*, Case No. CV 07-3490 (FMC) (PJWx), *Finch, et al., v. Merck & Co., et al.*, Case No. CV 07-3492 (FMC) (PJWx), *Horton, et al., v. Merck & Co., et al.*, Case No. CV 07-3493 (FMC) (PJWx), *Martin, et al., v. Merck & Co., et. al.*, Case No. CV 07-3495 (FMC) (PJWx), *Cecilia Smith, et al., v. Merck & Co., et al.*, Case No. CV 07-3497 (FMC) (PJWx), Evans, *et al., v. Merck & Co., et al.*, Case No. CV 07-4136 (FMC) (PJWx), *Goss, et al., v. Merck & Co., et al.*, Case No. CV 07-4172 (FMC) (PJWx), *Vasquez, et al., v. Merck & Co., et al.*, Case No. CV 07-4326 (FMC) (PJWx), *Moyer, et al., v. Merck & Co., et al.*, Case No. CV 07-4651 (FMC) (PJWx), and *Carrie Smith, et al., v. Merck & Co., et al.*, Case No. CV 07-4655 (FMC) PJWx).

These cases, like the above-captioned action, involve allegations regarding the prescription medication FOSAMAX® and will therefore call for the determination of the same or substantially related or similar questions of law and fact, and would entail substantial duplication of labor if heard by different judges. All 18 cases, including the above-captioned action, contain essentially the same allegations that certain injuries were caused by the prescription medication FOSAMAX®, and having all of these matters assigned to a single judge is appropriate.

PLEASE TAKE FURTHER NOTICE that, pursuant to Local Rule

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83-1.4, Merck hereby gives notice that the above-captioned case is the subject of or is related to Multidistrict Litigation that is pending in the United Stated District Court for the Southern District of New York, encaptioned In re Fosamax Products Liability Litigation, MDL-1789. On August 16, 2006, the Judicial Panel on Multidistrict Litigation ("MDL Panel") issued an order transferring 18 FOSAMAX® products liability cases to the United States District Court for the Southern District of New York (Keenan, J.) for coordinated pretrial proceedings under 28 U.S.C. § 1407. *In re Fosamax Products Liability Litigation*, MDL No. 1789. To date, the MDL Panel has issued 47 Conditional Transfer Orders, at least 131 cases involving FOSAMAX® have been transferred to MDL-1789, and there are a total of 371 cases pending in the MDL, including cases filed directly in the Southern District of New York.

All of the cases identified in the first paragraph above, which were filed in this District and were assigned to and/or related to the Honorable Florence-Marie Cooper, have previously been transferred from this District to the MDL. [1]

Merck will seek the transfer of this action to MDL-1789, and will, in the next several days, provide the MDL Panel with notice of this action pursuant to the "tag-along" procedure contained in the MDL Rules.

[1] Pursuant to a stipulation of the parties, the case of *Johnson v. Merck* was dismissed without prejudice by Judge Keenan in the United States District Court for the Southern District of New York, after a transfer of that case to MDL No. 1789.

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Dated: February 20, 2008

VENABLE LLP
DOUGLAS C. EMHOFF
JEFFREY M. TANZER

By /s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer
Attorneys for Defendant
Merck & Co., Inc.

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PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 2049 Century Park East, #2100, Los Angeles, California 90067.

On February 20, 2008, I served the foregoing document(s) described as **DEFENDANT MERCK & CO., INC.'S NOTICE OF RELATED CASES AND NOTICE OF PENDENCY OF OTHER PROCEEDINGS** on the interested parties in this action addressed as follows:
SEE ATTACHED SERVICE LIST

☒ By placing true copies thereof enclosed in a sealed envelope(s) addressed as stated above.

☐ **BY PERSONAL SERVICE (CCP §1011)**: I delivered such envelope(s) by hand to the addressee(s) as stated above.

☒ **BY MAIL (CCP §1013(a)&(b))**: I am readily familiar with the firm's practice of collection and processing correspondence for mailing with the U.S. Postal Service. Under that practice such envelope(s) is deposited with the U.S. postal service on the same day this declaration was executed, with postage thereon fully prepaid at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY (CCP §1013(c)&(d))**: I am readily familiar with the firm's practice of collection and processing items for delivery with Overnight Delivery. Under that practice such envelope(s) is deposited at a facility regularly maintained by Overnight Delivery or delivered to an authorized courier or driver authorized by Overnight Delivery to receive such envelope(s), on the same day this declaration was executed, with delivery fees fully provided for at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

Executed on February 20, 2008, at Los Angeles, California

☐ **(STATE)** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

☒ **(FEDERAL)** I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.

/s/ -- Jeffrey M. Tanzer
Jeffrey M. Tanzer

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UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION

Jacqueline Hill v. Merck & Co., Inc.,)
C.D. California, C.A. No. 8:08-65 ✓) MDL No. 1789

CONDITIONAL TRANSFER ORDER (CTO-48)

On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 115 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

It appears that the action on this conditional transfer order involves questions of fact that are common to the actions previously transferred to the Southern District of New York and assigned to Judge Keenan.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), this action is transferred under 28 U.S.C. § 1407 to the Southern District of New York for the reasons stated in the order of August 16, 2006, and, with the consent of that court, assigned to the Honorable John F. Keenan.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Southern District of New York. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

INVOLVED COUNSEL LIST (CTO-48)

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UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

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February 27, 2008

J. Michael McMahon, Clerk
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: MDL No. 1789 -- IN RE: Fosamax Products Liability Litigation

(See Attached CTO-48)

Dear Mr. McMahon:

I am enclosing a certified copy and one additional copy of a conditional transfer order filed by the Panel in the above-captioned matter on February 11, 2008. As stipulated in Rule 7.4(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), transmittal of the order has been stayed 15 days to give any party an opportunity to oppose the transfer. The 15-day period has now elapsed, no opposition was received, and the order is directed to you for filing.

The Panel's governing statute, 28 U.S.C. §1407, requires that the transferee clerk "...transmit a certified copy of the Panel's order to transfer to the clerk of the district court from which the action is being transferred."

A list of involved counsel is attached.

Very truly,

Jeffery N. Lüthi
Clerk of the Panel

By Dana L. Stewart
Deputy Clerk

Attachment

cc: Transferee Judge: Judge John F. Keenan
Transferor Judge: Judge Alicemarie H. Stotler
Transferor Clerk: Sherri R. Carter

JUDICIAL PANEL ON MULTIDISTRICT LITIGATION
Thurgood Marshall Federal Judiciary Building
One Columbus Circle, N.E.
Room G-255, North Lobby
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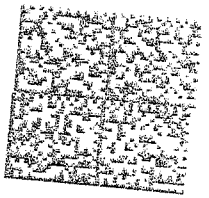

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